



January 27, 2012

VIA ECF

Honorable Tonianne J. Bongiovanni, U.S.M.J.
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
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Trenton, New Jersey 08608

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Re: *Takeda Pharmaceutical Company Limited et al. v. Zydus Pharmaceuticals USA Inc. et al.*, Civil Action No. 3:10-cv-01723-JAP-TJB

Dear Judge Bongiovanni:

We, along with Hogan Lovells, represent Plaintiffs, Takeda and Ethypharm¹, in this action. We seek an Order striking paragraphs 56-72 of an expert report submitted on behalf of Defendants Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (together, "Defendants"). Mere months before trial and near the end of the 30-month stay, Defendants included previously undisclosed invalidity arguments based on prior art in the Expert Report of Paula Meyer-Stout, Ph.D. ("Meyer-Stout Report", attached hereto as Exhibit A), dated January 17, 2012. In flagrant disregard of Local Patent Rule 3.7, Defendants had not sought leave to amend their contentions. For the reasons set forth below, Plaintiffs respectfully request that the Court strike paragraphs 56-72 of the Meyer-Stout Report.

1. Defendants Amended Their Invalidity Contentions But Did Not Assert Invalidity Based on Prior Art Against the Takeda Patents Until Opening Expert Reports

This is a patent infringement action under the Hatch-Waxman Act on four patents covering the Takeda Plaintiffs' Orally Disintegrating Tablet ("ODT") formulation of the blockbuster anti-ulcer drug Prevacid[®]. Three of the patents-in-suit, U.S. Patent Nos. 6,328,994 ("the '994 Patent"), 7,431,942 ("the '942 Patent"), and 7,875,292 ("the '292 Patent"), are assigned to Takeda (collectively, "Takeda patents").

Pursuant to Local Patent Rules 3.3 and 3.6, and the parties' joint discovery plan, Defendants served their Non-Infringement and Invalidity Contentions on August 16, 2010. A copy is attached hereto as Exhibit B. Defendants raised no invalidity contentions based on prior art against the Takeda patents. See Exh. B at pp.13-20 (blank columns under heading, "Basis for Prior-Art Based Invalidity

¹ "Plaintiffs" refers to Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc. (collectively, "Takeda"), and Ethypharm, S.A.

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Contentions.") On December 3, 2010, with leave of Court, Defendants served Amended Non-Infringement and Invalidity Contentions. A copy is attached hereto as Exhibit C. Defendants revised their Invalidity Contentions against the Takeda patents based on the written description requirement, 35 U.S.C. § 112, but did not assert invalidity against the Takeda patents based on prior art. See Exh. C at pp.13-20 (blank columns under heading, "Basis for Prior-Art Based Invalidity Contentions.")

Twenty months into the case, Defendants served Paula Meyer-Stout's Expert Report on January 17, 2012. Defendants contended for the first time that the Takeda patents are obvious in view of prior art. (Meyer-Stout Rept. ¶¶ 56-72.) Because Defendants based their previously undisclosed argument on publicly available prior art, their delay in stating these contentions was entirely within their control. Defendants did not seek leave from the Court to amend their Invalidity Contentions to make this obviousness challenge, as required by Local Patent Rule 3.7.

Plaintiffs' rebuttal expert reports are due on February 7; close of expert discovery is set for February 29. The 30-month stay in this action expires in mid-August of this year, and the Court has suggested that a trial in late spring/early summer would be in order. With trial mere months away, Defendants' belated invalidity contentions unquestionably prejudice Plaintiffs. Plaintiffs, to date, based their litigation strategy on Defendants' timely and disclosed contentions. Plaintiffs now do not have the "fair opportunity to counter" Defendants' argument to which they are "entitled." *Fleming v. Escort, Inc.*, No. CV 09-105-S-BLW, 2011 WL 1542126, at *4 (D. Idaho Apr. 21, 2011); see also *King Pharmaceuticals, Inc. v. Sandoz Inc.*, Civil Action No. 08-5974 (GEB), 2010 WL 2015258, at *2, 5 (D.N.J. May 20, 2010) (finding prejudice even though fact discovery was ongoing and expert discovery had not begun); *Tyco Healthcare Grp. LP v. Applied Med. Res. Corp.*, Civil Action No. 9:06-CV-151, 2009 WL 5842062, at *3 (E.D. Tex. Mar. 30, 2009) (finding prejudice and observing that "[w]hether or not Tyco would have to perform in-depth analysis or undertake a great deal of discovery to rebut Applied's assertions is irrelevant; the point is that Applied should have, and did not, disclose the combination in a timely manner"). Significantly, any attempt to cure the prejudice to Plaintiffs by delaying the proceedings (e.g., by extending expert discovery or allowing Plaintiffs' expert to file a supplemental expert report) will push back trial, endanger the 30-month stay and/or trigger the "fire drill" of a preliminary injunction.

2. Defendants' Flagrant Violation of the Local Patent Rules Bars their Reliance on Previously Undisclosed Invalidity Contentions

The Local Patent Rules with respect to disclosure of invalidity contentions based on prior art are crystal clear. A "party opposing an assertion of patent infringement shall provide to each party asserting patent infringement the written basis for its 'Invalidity Contentions,' " which "shall contain," among other things, "[t]he identity of each item of prior art that allegedly anticipates each asserted claim

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or renders it obvious." L. Pat. R. 3.3 and 3.6. Amendments to a party's invalidity contentions "may be made only by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7.

"[L]ocal patent rules are created to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases," and thus to prevent "litigation by ambush." *APP Pharms. LLC v. Ameridose, LLC*, Civil Action No. 10-4109, 2011 WL 6325975, at *1 (D.N.J. Dec. 6, 2011) (quotation omitted). As such, the rules "require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *King Pharmaceuticals*, 2010 WL 2015258, at *4 (denying motion to amend invalidity contentions), *appeal denied, judgment aff'd*, 2010 WL 4789950 (D.N.J. Sept. 8, 2010).

When a party flouts local patent rules by including previously undisclosed invalidity arguments in its expert reports, as Defendants have done here, courts nationwide² strike the offending material. See, e.g., *Fastek, LLC v. Steco*, Civil No. 10-cv-0972-MMA (CAB), 2011 WL 4499101, at *1 (S.D. Cal. Sept. 27, 2011) (striking previously undisclosed invalidity contentions as "not properly part of the expert's report"); *Fleming*, 2011 WL 1542126, at *4 ("To the extent [Defendant] is arguing that experts should be allowed to announce new invalidity contentions, that were not contained in a timely filing under Local Patent Rule 3.3, the Court has rejected that argument . . ."), *amended on reconsideration on other grounds*, 2011 WL 2173796 (June 2, 2011); *Brilliant Instruments, Inc. v. Guidetech, Inc.*, No. C. 09-5517 CW, 2011 WL 900369, at *2 (N.D. Cal. Mar. 15, 2011) ("Because Brilliant did not identify these patents as relevant prior art in its Invalidity Contentions, Dr. Kaliski may not use them as prior art to demonstrate invalidity. Accordingly, Dr. Kaliski's report is stricken to the extent that he relies on [that prior art]"); *Tyco Healthcare*, 2009 WL 5842062, at *3 (granting plaintiff's motion to strike and observing that experts are not "permitted to opine on obviousness combinations or motivations to combine that were never disclosed" in invalidity contentions); *Anascape, Ltd. v. Microsoft Corp.*, Civil Action No. 9:06-CV-158, 2008 WL 7180756, at *1 (E.D. Tex. May 1, 2008) (striking previously undisclosed invalidity contentions from an expert report and denying leave to amend); *Finisar Corp. v. DirecTV Grp., Inc.*, 424 F. Supp. 2d 896 (E.D. Tex. Mar. 28, 2006) (striking expert report).

It cannot be disputed that the paragraphs of Meyer-Stout's expert report addressing invalidity based on prior art against Takeda patents run afoul of the Local Patent Rules. Plaintiffs were "entitled to know all the art" Defendants "would be relying upon for [their] invalidity analysis in [their] final invalidity contentions."

² This District often relies on case law from other jurisdictions when construing the local patent rules. *King Pharmaceuticals*, 2010 WL 2015258, at *4 n.1 ("[T]he District of New Jersey developed its Local Patent Rules taking guidance from the Local Patent Rules of the Eastern District of Texas and the Northern District of California. The Court recognizes that the issues raised in the instant Motion have not been widely analyzed in this District and, therefore, finds it appropriate to consider decisions from these districts.").

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Fastek, 2011 WL 4499101, at *1 (striking previously undisclosed invalidity contentions as "not properly part of the expert's report").³ Paragraphs 56-72 of the Meyer-Stout Report, and the opinions set forth therein, should be stricken.⁴ Defendants cannot ambush Plaintiffs with their last-minute invalidity theory.

Plaintiffs are available for a teleconference to discuss the issues discussed above, if the Court so desires.

Respectfully,

s/John E. Flaherty

John E. Flaherty

cc: Counsel of record (via email)

Enclosures: Exhibits A-C (filed under seal)

³ Defendants cannot claim that there is no prejudice because their previously undisclosed invalidity argument is based on a handful of prior art references. See, e.g., *Fastek*, 2011 WL 4499101, at *1 (striking two references); *Brilliant Instruments*, 2011 WL 900369, at *2 (striking the two new references asserted for invalidity); *Tyco Healthcare*, 2009 WL 5842062, at *2-5 (striking expert report that did not rely on *any* new references, but used previously disclosed prior art against additional claims); *Anascope*, 2008 WL 7180756, at *3-4 (similar).

⁴ Plaintiffs note that Defendants will still be able to raise an invalidity attack against the Takeda patents, if they so choose, at trial. Defendants can continue relying on other invalidity arguments (e.g., based on written description) that were timely disclosed in their Invalidity Contentions. *Tyco Healthcare*, 2009 WL 5842062, at *4 (striking expert report and noting any harm to Defendants resulting from exclusion was "minimal" because they were not barred from using properly and timely disclosed arguments).